B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,256	08/20/2003	David H.A. Jones	2578-6077US	6153

24247 7590 03/29/2006

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,256	JONES ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	MAIL

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-11* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/1/2004*. 11/7/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 11/23/2005 and 2/27/2006. Claims 1-21 are pending. Claims 12-21 are withdrawn.

Election/Restrictions

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2005.

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally elected for the following reasons: claim 21 is drawn to a method for recombinant production of an IgA molecule and would have been grouped with the non-elected Group II invention in the restriction requirement sent 11/3/2005.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's request for clarification of the rules regarding status identifiers for non-elected claims in light of MPEP 821 and 37 CFR §1.142(b) is acknowledged. Examiner notes that election of an invention with or without traverse and simultaneous submission of a claim set wherein non-elected claims are identified as "original" or "currently amended" is ambiguous. If the reverse had occurred, i.e. Applicant identified *elected* claims within the claim set as "withdrawn," Examiner would also treat such a case as non-responsive in order to avoid any confusion with regard to which claims are truly elected. In both situations, this is done as a courtesy to Applicant *before* Examiner withdraws non-elected claims pursuant to 37 CFR §1.142(b) and MPEP 821. Therefore, the Notice of Non-compliant amendment was properly issued.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 3/1/2004 and 1/17/2006 are acknowledged. However, two of the references listed on the IDS submitted 1/17/2006 are not present in the file (Caravokyri, et al, Journal of Virology 69(11):6627-6633, 1995; and Ory, et al, Proc. Natl. Acad. Sci. 93:11400-

11406, 1996). For the sake of compact prosecution, Examiner has retrieved these documents and placed them into the file by way of inclusion on a PTO-892 form.

Specification

The disclosure is objected to because of the following informalities: the use of the trademark PER.C6™ has been noted in this application on page 4, paragraph 11 and page 5, paragraph 16, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology. In this instance, the trademark/trade name is used to identify/describe a human embryonic restinobast cell line containing Advenovirus serotype 5 (Ad5) E1A and E1B-encoding sequences under the control of the human phosphoglycerate kinase (PGK) promoter. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Priority

Applicant's claim to priority as a continuation-in-part of Patent Application No. 09/549,363, filed 4/14/2000, which claims benefit of 60/129,452, filed 4/15/1999, is acknowledged. However, as the instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format, and because the Patent Application 09/549,363 does not disclose such a cell wherein the cell comprises such a nucleic acid encoding an IgA molecule, priority is granted only to the filing date of the instant application: 8/20/2003.

Claim Objections

Claims 9-11 are objected to because of the following informalities: Claims 9-11 recite "wherein said cell, when seeded at 0.5 x 106 cells/well" in line 1 of each claim. Claims 9-11 should instead recite "wherein said cell, when seeded at 0.5 x [[106]] 10^6 cells/well". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 recite "wherein said cell is derived from" in line 1. Claims 3-5 are vague and indefinite in that it is unclear what the number or types of steps involved in said "deriving" are. Are there structural characteristics or phenotypes associated with the derived cells; e.g. would a retina cell passaged many times under mutating conditions be encompassed?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is drawn to or encompasses a cell expressing E1A and E1B proteins of an adenovirus and further comprising recombinant nucleic acid encoding an IgA molecule in expressable format. The claim further encompasses such cells deposited under ECACC number 96022940. The application discloses a retinoblast cell line that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. It is

noted that the retinoblast cell culture (Dep. Ref. 96022940) has been accepted by the ECACC as a patent deposit in accordance with the Budapest Treaty of 1977 on February 29, 1996. However, in order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to cells expressing E1A and E1B proteins of an adenovirus and comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein the cell, when seeded at 0.5×10^6 cells/well and cultured in a 6-well tissue culture plate at 37°C in DMEM with 10% serum under an atmosphere containing 10% $C0_2$, produces at least 5, 20 or 40 pg IgA/seeded cell/day. The claims encompass any cell as long as it expresses adenoviral E1A and E1B proteins and comprises a recombinant nucleic acid encoding an IgA molecule. The claims do not provide any structural information with regard to the types of cells or the sequences of the recombinant nucleic acids necessary for production of at least 5, 20 or 40 pg IgA/seeded cell/day. Thus, the rejected claims comprise a set cells and nucleic acid sequences that are defined by the amount of protein which is produced.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes PER.C6 cells transfected with pEpcamIgA. The PER.C6 cells express E1A and E1B proteins of an adenovirus (Ad5), and after transfection, produce IgA (page 5, paragraph 16 and page 11, paragraph 35). The specification describes the recombinant nucleic acid as containing a "DNA encoding a kappa light chain and an alpha1 heavy chain, both preceded by a CMV promoter" (page 10, paragraph 34). No description is provided of any other cell or any other recombinant DNA which can be used to produce at least 5, 20 or 40 pg Ig/seeded cell/day when cultured under the conditions listed in claims 9-11.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of one cell which expresses adenoviral E1A and E1B proteins and which comprising a recombinant nucleic acid sequence capable of producing at least 5, 20, or 40 pg

IgA/seeded cell/day. The results are not necessarily predictive of any other cells or recombinant nucleic acids capable of achieving such high production of IgA. Thus it is impossible to extrapolate from the example described herein those nucleic acid molecules coupled with those cells that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set cells expressing E1A and E1B proteins and recombinant nucleotides encoding an IgA molecule such that, when seeded at 0.5×10^6 cells/well and cultured in a 6-well tissue culture plate at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO_2, the cells produce at least 5, 20 or 40 pg IgA/seeded cell/day. Ruben et al (US Patent No. 6,475,753) describe cells that express E1A and E1B proteins of an adenovirus and which comprise a recombinant nucleotide encoding an IgA molecule (see column 205, lines 45-50; and column 160, lines 13-18). However, Ruben et al do not describe the cells as capable of producing at least 5, 20 or 40 pg IgA/seeded cell/day when seeded as directed in claims 9-11.

Given the very large genus of cells and recombinant nucleic acid molecules encompassed by the rejected claims, and given the

limited description provided by the prior art and specification with regard to the E1A- and E1B-expressing cells further comprising recombinant nucleic acids encoding an IgA molecule capable of such high immunoglobulin production, the skilled artisan would not have been able to describe the broadly claimed genus of E1A- and E1B-expressing cells comprising recombinant nucleic sequences that when seeded at 0.5 x 10^6 cells/well and cultured in a 6-well tissue culture plate at 37°C in DMEM with 10% serum under an atmosphere containing 10% CO_2, produce at least 5, 20 or 40 pg IgA/seeded cell/day. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those cells in combination with those recombinant nucleic acid sequences that satisfy the production limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 9-11.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting

rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-35 and 41-42 of copending Application No. 10/234,007. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein said cell is a human cell, wherein said cell is derived from a retina cell, wherein said cell is derived from a primary cell and wherein

said cell is derived from a cell deposited under ECACC number 96022940. The claims are further drawn to such a cell in culture.

The copending claims are drawn to a species of the instant claims' genus insofar as the copending claims are drawn to a *eukaryotic* cell for producing a protein. The copending claims are also drawn to species of the instant claims' genus insofar as the copending claims are further drawn to said eukaryotic cell comprising: nucleotide sequences encoding adenoviral E1A and E1B proteins; wherein the genome of the eukaryotic cell does not comprise a nucleotide sequence encoding a structural adenoviral protein; and wherein the recombinant nucleotide sequence encoding the protein is under the control of a heterologous promoter. However, the copending claims are drawn to a genus of the instant claims' species insofar as the copending claims are drawn to a cell comprising a recombinant nucleotide sequence encoding any protein comprising the variable domain of an immunoglobulin, whereas the instant claims are drawn to the more narrow set of recombinant nucleic acids encoding an immunoglobulin IgA molecule. In this respect, it would have been obvious to utilize a eukaryotic cell in the instant invention, because the copending application's disclosure contains embodiments with eukaryotic cells such as

human cells that comprise recombinant nucleic acids encoding an immunoglobulin molecule (page 12, paragraph 55). One would have had a reasonable expectation of success when using a eukaryotic cell because the 10/234,007 disclosure recites the use of a eukaryotic cell which produces a monoclonal antibody in a human retinoblast cell (page 11, paragraph 51). Both sets of claims are drawn to human cells, cells derived from retina cells, cells derived from primary cells as well as cells deposited under ECACC number 96022940.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 17-18 of copending Application No. 10/790,562. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein said cell is a human cell, wherein said cell is derived from a retina cell,

wherein said cell is derived from a primary cell and wherein said cell is derived from a cell deposited under ECACC number 96022940. The claims are further drawn to such a cell in culture.

The copending claims are drawn to a species of the instant claims insofar as they are drawn to a *eukaryotic* cell for producing a proteinaceous substance, whereas the istant claims are drawn to any cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The copending claims are also drawn to a species of the instant claims insofar as eukaryotic cell of the copending claims comprises a genome that does not comprise a nucleotide sequence encoding a structural adenoviral protein and the cell does not express a structural adenoviral protein. The copending claims are drawn to a genus of the instant claims species insofar as the instant claims are drawn to a cell encoding an IgA molecule in expressible format whereas the copending claims are drawn to a cell encoding any proteinaceous substance. In this respect, it would have been obvious to utilize a eukaryotic cell in the instant invention encoding an immunoglobulin molecule, because the copending application contains embodiments with eukaryotic cells such as human cells for producing a protein (see page 11, paragraph 51). Both sets of claims are drawn to human cells,

cells derived from retina cells, cells derived from primary cells as well as cells deposited under ECACC number 96022940. Finally, both sets of claims are drawn to such a cell in culture.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-15 and 18-19 of copending Application No. 11/271,090. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein said cell is a human cell, wherein said cell is derived from a cell deposited under ECACC number 96022940, an immortalized human retina cell. The copending claims are drawn to such a cell wherein the cell comprises a recombinant nucleic acid encoding an IgM molecule.

It would have been obvious for one of ordinary skill in the art to replace the IgA molecule encoded by the cell of the

instant application for the IgM molecule of the copending application because both the copending application's disclosure as well as the instant disclosure recite both classes of Ig molecule. Furthermore, one of ordinary skill in the art would have had reasonable expectation of success when substituting the IgA molecule for the IgM molecule because the 11/271,090 disclosure teaches that, although IgG could be produced at high levels by human cells, IgM was not expected to be produced at similar levels due to its larger size (see page 7, paragraph 27 of the 11/271,090 disclosure). Thus, other immunoglobulins of comparable size to IgM, such as IgA, would similarly be expected to be produced under similar conditions at levels comparable to those for IgG and IgM when cultured in the same cell and under the same conditions. One of ordinary skill in the art would have been motivated to make such a substitution because the 11/271,090 disclosure teaches that immunoglobulins, including IgA molecules, can be used for such things as antimicrobials (page 4, paragraph 11) and possibly treatment of allograft rejection (page 4, paragraph 10).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/499,298. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein said cell is a human cell, wherein said cell is derived from a retina cell, wherein said cell is derived from a primary cell and wherein said cell is derived from a cell deposited under ECACC number 96022940. The claims are further drawn to such a cell in culture. The copending claims are drawn to a host cell comprising adenovirus E1 sequences and further comprising recombinant nucleic acid encoding an immunologically active bivalent multimeric antibody fragment, and/or a precursor thereof, functionally linked to one or more sequences capable of driving expression of said fragment in said host cell. The instant claims are drawn to a species of the copending claims' genus insofar as the claims are drawn to a recombinant nucleic acid encoding an IgA molecule in expressible format whereas the copending claims are drawn to any recombinant nucleic acid encoding an immunologically active bivalent

multimer antibody fragment, and/or a precursor thereof. It would have been obvious for one of ordinary skill in the art to use an immunoglobulin molecule (of which IgA is one) of the instant invention in the invention of the copending claims because the 10/499,298 disclosure contains an immnoglobulin molecule as a preferred embodiment (see, e.g. page 28, lines 24-27).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-50 of copending Application No. 11/039,767. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format. The claims are further drawn to such a cell wherein said cell is a human cell, wherein said cell is derived from a retina cell, wherein said cell is derived from a primary cell and wherein said cell is derived from a cell deposited under ECACC number

96022940. The claims are further drawn to such a cell in culture. The copending claims are drawn to a host cell comprising at least one exogenously introduced nucleic acid sequence encoding an immunoglobulin light chain and at least two different immunoglobulin heavy chains. The instant claims are further drawn to a cell derived from a primary cell and wherein said cell is derived from a cell deposited under ECACC number 96022940. The instant claims are drawn to a species of the copending claims insofar as the instant claims are drawn to a cell expressing E1A and E1B proteins of an adenovirus. In this respect it would have been obvious for one of ordinary skill in the art to utilize such a cell in the invention of the 11/039,767 application because the 11/039,767 disclosure teaches such a cell, the PER.C6 cell, as a preferred embodiment (see, e.g., page 21, paragraph 68). One of ordinary skill in the art would have been motivated to use the PER.C6 cell because the 11/039,767 disclosure teaches that it can be used to produce proteins with a human glycosylation pattern (ibid). Based upon such teachings and the high skill level of one of ordinary skill in the art, it would have been obvious to use such a cell as a species to the copending claims' genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruben et al (US Patent No. 6,475,753). Ruben et al teach a 293 cell which expresses E1A and E1B proteins of an adenovirus and which further comprises an adenovirus vector (see column 205, lines 45-50). Ruben et al further teach that the adenovirus vector can be used "such that it encodes and expresses polypeptides of the invention" (column 205, lines 20-23). Ruben et al further teach that the polypeptides of the invention comprise immunogenic or antigenic

epitopes fused to the constant domain of immunoglobulins such as IgA (column 160, lines 13-18). Ruben et al also teach antibody polypeptides which can be of any type (e.g. IgA) or any class e.g., IgA1 or IgA2 (column 161, lines 34-38). Therefore, Ruben et al teach a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising at least one recombinant nucleic acid encoding an IgA molecule in expressible format. Because 293 cells are human cells derived from primary cells (human embryonic kidney cells), Ruben et al also teach the limitations of claims 2 and 4. Ruben et al also teach that the antibody can be a human antibody, thus meeting the claim limitation of claim 7. Because Ruben et al teach a cell comprising at least one adenoviral vector comprising recombinant nucleic acid encoding an IgA molecule in expressible format, it meets the limitation of claim 6 which recites such a cell "wherein said cell comprises between one and twenty copies of said recombinant nucleic acid encoding the IgA molecule."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben et al in view of Fallaux et al (WO/9700326).

Ruben et al teach, as recited above, a 293 cell which expresses E1A and E1B proteins of an adenovirus and which further comprises an adenovirus vector (see column 205, lines 45-50). Ruben et al further teach that the adenovirus vector can be used "such that it encodes and expresses polypeptides of

the invention" (column 205, lines 20-23). Ruben et al further teach that the polypeptides of the invention comprise immunogenic or antigenic epitopes fused to the constant domain of immunoglobulins such as IgA (column 160, lines 13-18). Ruben et al also teach antibody polypeptides which can be of any type, e.g. IgA, or any class e.g., IgA1 or IgA2 (column 161, lines 34-38). Therefore, Ruben et al teach a cell expressing E1A and E1B proteins of an adenovirus, said cell comprising at least one recombinant nucleic acid encoding an IgA molecule in expressible format.

Ruben et al do not teach such a cell wherein said cell is derived from a retina cell or wherein said cell is derived from a cell deposited under ECACC number 96022940.

Fallaux et al teach a human embryonic retinoblast cell transfected with pIG.E1A.E1, resulting in seven clones called PER cells, including PER.C6 (page 17, lines 25-37; and page 18, lines 1-13). Fallaux et al teach that this cell line has been deposited at the ECACC under number 96022940 (page 30, lines 3-4). These cells express E1A and E1B proteins (page 25, lines 15-17; page 30, lines 22-34 and Figure 7). Fallaux et al further teach that the Ad vectors for use in these cells "will also contain a transgene linked to promoter sequence to govern expression of the transgene" and that the vectors of their

invention can accommodate up to 38 kb of foreign DNA (paragraph bridging pages 12 and 13; and page 17, lines 6-8). Fallaux et al also teach that the yield of recombinant adenovirus obtained after inoculation of both PER.C6 and 293 cells were much higher in the PER.C6 cells than in the 293 cells (page 32, lines 6-15 and Table 2), and that such a packaging system prevents the generation of replication competent adenovirus (page 33, lines 19-25).

It would have been obvious for one of ordinary skill in the art to substitute the PER.C6 cell of Fallaux et al for the 293 cell of Ruben et al because Fallaux et al teach that either the 293 cell or the PER.C6 can be used for production of an adenoviral vector with E1 deletions.

One of ordinary skill in the art would have been motivated to substitute the 293 cell of Ruben et al with the PER.C6 cell of Fallaux et al because Fallaux et al teach that the PER.C6 cell yields greater amount of adenovirus after inoculation than does the 293 cell.

Based upon the teachings of the cited references, including the fact that both Fallaux et al and Ruben et al teach a eukaryotic cell expressing E1A and E1B proteins for the production of a recombinant adenovirus and expression of a transgene, and the fact that Fallaux et al teach that production

of the recombinant adenovirus is possible in both 293 and PER.C6 cells, and based upon the high skill level of one of ordinary skill in the art, there would have been a reasonable expectation of success when substituting the PER.C6 cell as taught by Fallaux et al with the 293 cell to generate a eukaryotic cell expressing E1A and E1B proteins, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format as taught by Ruben et al.

Allowable Subject Matter

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If

Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

March 14, 2006

NANCY VOGEL
PRIMARY EXAMINER

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.